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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| COLLINS, CYNTHIA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/821,839 | MA, HONG | |
| | Examiner | Art Unit | |
| | Cynthia Collins | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The amendments filed May 3, 2004 and August 16, 2004 have been entered.

Claims 1-26 are cancelled.

Claims 27-36 are newly added.

Claims 27-36 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### *Claim Rejections - 35 USC § 112*

Claims 27-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth for claims 1-8 and 12-13 in the office action mailed December 30, 2003.

Applicant's arguments filed August 16, 2004, have been fully considered but they are not persuasive.

Applicant submits that the rejection should not be applied to the presently pending claims. Applicant points out that the newly submitted claims are directed to isolated nucleic acid molecules having SEQ ID NO:1 and their very close homologs (greater than 95% identity), encoding a cyclin domain-containing polypeptide. Applicant submits that the specification clearly teaches that insertional disruption within the coding region of this nucleic acid results in

several phenotypic changes that lead to abnormal pollen formation, and that the specification further teaches how to use SEQ ID NO:1 or its close homologs to make a transgenic plant that has a similar loss of the SEQ ID NO:1 gene product as does the null mutant described in the specification. Applicant also maintains that the art of disrupting gene expression in plants is not unpredictable, and that undue experimentation would not be required to use the nucleic acid molecules of the invention for such purposes because such methods have been commonly used for many years since 1990 by biologists in all fields. Applicant maintains that while some experimentation may be required to identify the best means by which to disrupt gene expression, the methods are currently sufficiently commonplace that the experimentation would be of a routine nature. (reply pages 6-7)

The rejection is maintained because the application of methodologies such as antisense or cosuppression to test a particular polynucleotide sequence for its ability to impart a particular phenotype is unpredictable. This unpredictability is not negated by the fact that methods for disrupting gene expression have been used for many years since 1990 by biologists in all fields, as this unpredictability is a consequence of the unique physical characteristics of each polynucleotide sequence, which characteristics vary between different polynucleotide sequences. In this regard neither the specification nor the prior art provide guidance with respect to how to use a polynucleotide sequence of SEQ ID NO:1 to achieve the same phenotypic effect as insertional disruption within the coding region of SEQ ID NO:1. Absent such guidance it would require undue experimentation for one skilled in the art to determine how to use SEQ ID NO:1, or sequences homologous thereto, to produce transgenic plants exhibiting male sterility and failure to maintain homologue attachment during meiotic prophase I, as one skilled in the art

would have to resort to trial and error testing of each of the claimed sequences, as well as subfragments thereof, to determine their phenotypic effect, if any, on a plant transformed therewith.

Claim 27, and claims 28-33 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth for claim 1 in the office action mailed December 30, 2003.

Applicant's arguments filed August 16, 2004, have been fully considered but they are not persuasive.

Applicant submits that this rejection should not be applied to the currently pending claims. Applicant points out that claim 27 now recites an isolated nucleic acid molecule that encodes a cyclin-containing polypeptide that functions to maintain normal pairing of homologous chromosomes during meiotic prophase 1 in meiotic cells of plants. Applicant also points out that the specification teaches, and it is known in the art, that cyclins are regulatory proteins, and that the specification further teaches several specific phenotypic features associated with loss of function of the protein, which further delineates the function of the protein. Applicant maintains that the recitation of function in claim 27, combined with the teachings in the specification and the knowledge of the skilled artisan, would clearly inform one of the skill in the art as to the metes and bounds of the claimed invention (reply page 8).

The rejection is maintained because recitation that the isolated nucleic acid molecule encodes a cyclin-containing polypeptide that functions to maintain normal pairing of

homologous chromosomes during meiotic prophase 1 in meiotic cells of plants (as compared to "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes" previously recited in claim 1) does not clarify what function the encoded polypeptide performs given that the specification at page 8 lines 28-30 indicates that the encoded polypeptide activates a cyclin-dependent kinase to regulate the activities of other proteins that maintain homolog attachment. Further, that the art teaches that cyclins are regulatory proteins does not clarify what function the encoded polypeptide performs as the claim does not indicate that the encoded protein is a cyclin protein, and as the specification does not establish that the encoded protein is a cyclin protein. Additionally, that the specification further teaches several specific phenotypic features associated with loss of function of the protein does not clarify what function the encoded polypeptide performs, as the phenotypic features associated with loss of function of a protein may not be directly affected by the protein in question.

***Claim Rejections - 35 USC § 101 and § 112***

Claims 27-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, and under 35 U.S.C. 112, first paragraph, because one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth for claims 1-8 and 12-13 in the office action mailed December 30, 2003.

Claims 27-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not

know how to use the claimed invention, for the reasons of record set forth for claims 1-8 and 12-13 in the office action mailed December 30, 2003.

Applicant's arguments filed August 16, 2004, have been fully considered but they are not persuasive.

Applicant submits that the rejection should not be applied to the presently pending claims because the specification establishes empirically that disruption of the protein coding region of SEQ ID NO:1 results in abnormal pollen formation, which has a specific and substantial utility in male sterility. Applicant also submits that though the specification provides no working examples the specification further teaches how to use SEQ ID NO:1 to create transgenic plants wherein the endogenous gene expression is disrupted. Applicant additionally submits that the relevant art is sufficiently well developed that the skilled artisan would recognize the asserted utility of SEQ ID NO:1 and its close homologs for this purpose as a credible utility. (reply pages 8-9)

The rejection is maintained because the disruption of the protein coding region of SEQ ID NO:1 in planta does not establish a specific and substantial utility for an isolated nucleic acid encoding said protein, since the phenotypic effects are associated with the absence of the protein rather than the presence of the protein or its coding sequence. The rejection is also maintained because the specification does not provide sufficient guidance for using SEQ ID NO:1 to create transgenic plants wherein the endogenous gene expression is disrupted and the desired phenotypic effect is achieved. Further, the outstanding rejection was not predicated on the credibility of the asserted utility.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

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